



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁶ : A61B 17/32</p>	<p>A1</p>	<p>(11) International Publication Number: WO 97/37599</p> <p>(43) International Publication Date: 16 October 1997 (16.10.97)</p>
<p>(21) International Application Number: PCT/US97/05768</p> <p>(22) International Filing Date: 7 April 1997 (07.04.97)</p> <p>(30) Priority Data: 08/629,217 8 April 1996 (08.04.96) US</p> <p>(71) Applicant: BLOOM, Leonard [US/US]; Suite 905, 401 Washington Avenue, Towson, MD 21204 (US).</p> <p>(71)(72) Applicants and Inventors: ABIDIN, Michael, R. [US/US]; 5808 Appleford Drive, Alexandria, VA 22310 (US). LEHMBECK, Steven, P. [US/US]; 8 Roxburgh Court, Baltimore, MD 21236 (US).</p> <p>(74) Agent: GAMSON, Robert, M.; Bloom & Kreten, Suite 905, 401 Washington Avenue, Towson, MD 21204 (US).</p>		<p>(81) Designated States: AL, AM, AU, BA, BB, BG, BR, CA, CN, CU, CZ, EE, GE, HU, IL, IS, JP, KG, KP, KR, LC, LK, LR, LT, LV, MD, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TR, TT, UA, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>
<p>(54) Title: DISPOSABLE GUARDED FINGER SCALPEL FOR INSERTING A LINE IN A PATIENT AND BLADE THEREFOR</p> <p>(57) Abstract</p> <p>A kit for installing a central line in a patient includes a guarded finger scalpel (10), a needle (100) with a guide wire (103), and a catheter. The guarded finger scalpel has a blade (24) with a relatively blunt tip (305), thereby avoiding an accidental or inadvertent cut or nick of the patient's vein in the process of enlarging the puncture in the patient's skin previously made by the needle.</p> <div data-bbox="727 1171 1075 1415" data-label="Image"> </div> <div data-bbox="763 1520 1354 1902" data-label="Image"> </div>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

DISPOSABLE GUARDED FINGER SCALPEL FOR INSERTING
A LINE IN A PATIENT AND BLADE THEREFOR

CROSS REFERENCE TO RELATED APPLICATIONS

The present invention constitutes a continuation-in-part of application Serial No. 08/287,123 filed August 8, 1994 which, in turn, is a continuation-in-part of application Serial No. 08/079,985 filed June 18, 1993 and issued on December 6, 1994 as United States Letters Patent No. 5,370,654, the disclosures of which are incorporated herein in their entirety.

FIELD OF THE INVENTION

The present invention relates to a finger scalpel for making a small cut or incision in a patient's skin to facilitate insertion of a catheter, and more particularly, to a guarded finger scalpel to prevent inadvertent or accidental nicks or cuts incurred by any of the health care providers involved in using the finger scalpel or in the subsequent clean up and disposal thereof.

BACKGROUND OF THE INVENTION

In the process of establishing a line in a patient (as for example, during a heart bypass operation) a catheter is inserted into the patient. The purpose of the catheter may be to position a sensor or other device within the patient or to inject a medication or a dye into the patient. In order to insert the catheter, it is first necessary to insert a guide wire through the patient's skin and to locate one of the patient's veins (or other vessel, body cavity or organ). The guide wire comprises a flexible cable which is inserted through a puncture in the patient's skin, the puncture being made by a needle. Since the puncture is relatively small compared to the catheter, and since the catheter is relatively soft and flexible and may bend, it is

necessary to enlarge the puncture by making a small incision or cut substantially at the puncture or adjacent thereto.

This relatively small cut is made by a finger scalpel. The finger scalpel comprises a surgical blade attached to a small plastic handle that is grasped, typically, between the surgeon's thumb and forefinger.

After the cut is made, the surgeon merely drops the finger scalpel on the tray or on the patient's gurney. Since the blade is exposed (and usually contains blood or bodily fluids) this is a hazardous situation. The danger occurs in using the finger scalpel, or in cleaning up the operating room or patient's room, or in subsequent disposal of the used scalpel.

Accidental or inadvertent contact with the unguarded finger scalpel often results in the health care provider being nicked or cut, and exposure with the blood or bodily fluids on the blade may result in the health care provider sero-converting and thus becoming infected with Hepatitis B or the deadly HIV ("AIDS") virus.

Even if an infection does not occur, repeated testing and observation is necessary whenever a known AIDS patient is involved. This testing is worrisome, inconvenient and costly.

Conversely, there is also a risk to the patient in the event the surgeon or other health care provider is infected with AIDS or any contagious disease.

While no specific data is available with regard to finger scalpels, the risk is at least comparable to the problems associated with needle sticks. A study was made by the Needle Stick Surveillance Group of the C.D.C. (Centers for Disease Control). Out of 3,978 needle sticks from patients known to be HIV positive, 13 health care workers became infected---roughly 1 out of 300. Thus, from a single needle stick while treating an AIDS patient in an operating room or other environment, the chances are roughly 1 out of 300 that the surgeon, nurse or other individual health care provider will sero-convert and become HIV positive.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a guarded finger scalpel which substantially eliminates

inadvertent or accidental contact with the blade, thereby preventing the spread of infectious diseases.

It is another object of the present invention to provide a guarded finger scalpel having a retracted blade; such that when the scalpel is grasped or squeezed between the surgeon's thumb and forefinger, the blade is advanced and exposed for use; and such that when the scalpel is released, the blade is automatically retracted to its original position and is thereby guarded against accidental or inadvertent contact.

It is a further object of the present invention to provide a lock-off means to prevent movement of the blade relative to the guard following use of the guarded finger scalpel during a surgical procedure, thereby preventing accidental nicks or cuts during clean-up.

In accordance with the teachings of the present invention, the guarded finger scalpel includes a body normally grasped between a surgeon's thumb and forefinger. This body includes a blade guide means having a forward portion provided with an opening formed therein. A blade is slidably guided within the blade guide means and has respective sides. A pair of spring arms are connected to the blade and extend laterally of the blade on respective sides thereof. These spring arms are manually squeezed towards each other, thereby advancing the blade outwardly through the opening in the forward portion of the blade guide means in the body. Conversely, the blade is automatically retracted within the body when the spring arms are released to return to their original position.

In one embodiment, the body comprises a substantially rectangular frame having top and bottom walls and side portions provided with respective openings formed therein; the spring arms extend laterally through the openings, respectively, and are confined by the top and bottom walls of the frame.

In another embodiment, the body is substantially resilient and has respective side walls, and the respective spring arms are confined within the resilient body and engage the respective side walls thereof. With this arrangement, the respective side walls of the resilient body may be squeezed together to thereby deflect the spring arms towards each other.

Viewed in another aspect, the present invention constitutes an improvement in the method of inserting a line in a patient, wherein a needle is used to make a puncture in the patient's skin to locate a vein (or other vessel, cavity or organ) in the patient. A guide wire is inserted through the needle and through the puncture and into the patient, and the needle is removed. A catheter is inserted over the guide wire and into the patient, the wire being removed when the catheter is installed. The improvement includes the steps of providing a guarded finger scalpel having a covered blade, manually grasping the guarded finger scalpel and advancing the blade, making a cut in the patient's skin substantially at the puncture before the catheter is inserted over the guide wire, thereby facilitating inserting of the catheter, and automatically retracting the blade within the guarded finger scalpel, thereby preventing nicks or cuts due to accidental or inadvertent contact with the scalpel during use, clean-up or disposal thereof.

Viewed in still another aspect, the present invention provides a finger scalpel for use by a surgeon in installing a line in a patient in a hospital, wherein the finger scalpel is part of a disposable kit, and wherein the finger scalpel includes a body normally intended to be grasped between the surgeon's thumb and forefinger, the body having a blade mounted thereon. In accordance with the teachings of the present invention, a guard is provided on the body. The guard has a normal position covering the blade and preventing accidental contact therewith. A resilient means maintains the guard in the normal position thereof, such that the resilient means may be manually opposed as the finger scalpel is grasped by the surgeon, thereby exposing the blade relative to the guard. A lock-off means independent of the resilient means is provided. The lock-off means is operative in the normal position of the guard and prevents blade exposure, such that the clean-up personnel in the hospital are protected against nicks or cuts during disposal of the kit.

In a preferred embodiment, the lock-off means includes a lock-off button carried transversely by one of the side walls of the frame.

The inner member within the frame has a pocket formed therein. The lock-off button may be pushed inwardly of the frame

and received within the pocket in the inner member, thereby locking the inner member to the frame and preventing relative sliding movement therebetween.

In another embodiment, the look-off button is carried on a depressible tang formed on the one side wall of the frame.

The present invention also provides an improved kit for installing a central line in a patient. The kit includes, in combination, a needle for making a puncture in the patient's skin above one of the veins, a catheter with a guide wire, and a guarded finger scalpel having a blade attached thereto for enlarging the puncture in the patient's skin. A guard means on the guarded finger scalpel has a normal position in which the blade is covered and further has a retracted position in which the blade is exposed. Thus, the guard means is actively disarmed and moved from its normal position into its retracted position when the guarded finger scalpel is grasped, and the guard means is passively armed and returned to its normal position when the guarded finger scalpel is released. Moreover, the blade includes a tip portion having a front edge and a lower edge forming an acute angle therebetween, and this acute angle is sufficiently large to prevent the blade from cutting into the vein adjacent to the puncture in the patient's skin.

This acute angle is greater than 45° and, in a preferred embodiment, is approximately 60° .

These and other objects of the present invention will become apparent from a reading of the following specification taken in conjunction with the enclosed drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of one embodiment of the guarded finger scalpel of the present invention.

Fig. 2 is a cross-sectional view thereof, taken along the lines 2-2 of Fig. 1, and showing the respective spring arms connected to the blade, and further showing the spring arms extending through respective openings formed in the side portions of the rectangular frame.

Fig. 3 is a cross-sectional view thereof, taken along the lines 3-3 of Fig. 2, and showing the blade within the blade guide means.

Fig. 4 is a pictorial view showing the guarded finger scalpel being grasped by the surgeon.

Fig. 5 is a further pictorial view, corresponding substantially to Fig. 4, but showing the respective spring arms of the guarded finger scalpel being squeezed between the surgeon's thumb and forefinger to advance the blade out of the blade guide means.

Fig. 6 is an exploded perspective view, showing the assembly of the components of the guarded finger scalpel of Fig. 1.

Fig. 7 is a side elevation of a second embodiment of the guarded finger scalpel of the present invention with certain parts thereof broken away and sectioned to show the blade fully retracted within the body of the guarded finger scalpel.

Fig. 8 corresponds substantially to Fig. 7, but shows the resilient body of the guarded finger scalpel being squeezed between the surgeon's thumb and forefinger to advance the blade through an opening in the body of the guarded finger scalpel.

Fig. 9 is a top plan view corresponding to Fig. 7, with certain parts broken away, and showing a pair of spring arms connected between respective side portions of the blade and the resilient body of the guarded finger scalpel.

Fig. 10 is a further top plan view with certain parts broken away and sectioned, corresponding substantially to Fig. 9, but showing the body squeezed to deflect the spring arms to extend the blade.

Figs. 11-21 are pictorial views showing the sequence of using the guarded finger scalpel to make a cut (or cuts) in the patient to enable a catheter to be inserted into the patient.

Fig. 11 shows the needle making a puncture in the patient's skin to locate a vein, and further shows (in exploded relationship thereto) a flexible guide wire about to be inserted into the needle.

Fig. 12 shows the guide wire inserted into the vein, and further shows the needle being withdrawn therefrom.

Fig. 13 is a cross-sectional view thereof, taken along the lines 13-13 of Fig. 12, and drawn to an enlarged scale.

Fig. 14 shows the scalpel being picked up by the surgeon.

Fig. 15 shows the resilient body of the scalpel being squeezed between the surgeon's thumb and forefinger to thereby advance the blade out of the body of the guarded finger scalpel.

Fig. 16 shows the blade being used to make a small cut (or cuts) at the puncture in the patient's skin or substantially adjacent thereto, thereby enlarging the puncture to facilitate insertion of the catheter.

Fig. 17 shows the guarded finger scalpel being released to automatically retract the blade.

Fig. 18 shows the catheter being inserted over the guide wire, concentrically thereof.

Fig. 19 shows the catheter being inserted through the cut and into the patient's vein.

Fig. 20 is a cross-sectional view thereof, taken along the liens 20-20 of Fig. 19, and drawn to an enlarged scale.

Fig. 21 is a further cross-sectional view, corresponding substantially to Fig. 20, but showing the guide wire being withdrawn from the catheter in the patient's vein.

Fig. 22 is a schematic block diagram showing the preferred method of using the guarded finger scalpel of the present invention.

Fig. 23 is a perspective view of a further embodiment of the present invention, wherein a lock-off means is provided to lock the blade in its retracted position and prevent further movement of the blade relative to the guard on the frame.

Fig. 24 is a portion of Fig. 23, drawn to an enlarged scale, and showing a lock-off button on the frame.

Fig. 25 is a cross-sectional view thereof, taken along the liens 25-25 of Fig. 24 and drawn to an enlarged scale, and showing the pocket formed within the inner member.

Fig. 26 is a further cross-sectional view, corresponding substantially to Fig. 25, but showing the lock-off button pushed inwardly and received within the pocket formed in the inner member, thereby locking the inner member and hence the blade in its retracted position.

Fig. 27 is a longitudinal sectional view, taken along the lines 27-27 of Fig. 23 and drawn to an enlarged scale, and showing the inner member being retracted into its normal position on the frame.

Fig. 28 is a further longitudinal sectional view, corresponding substantially to Fig. 27, but showing the inner member fully retracted within the frame and the lock-off button pushed inwardly and received within the pocket on the inner member, thereby locking the inner member to the frame and preventing further movement of the inner member relative to the frame.

Fig. 29 is a perspective view of a further embodiment, whereby the lock-off button is carried by a depressible tang formed on a side wall of the frame.

Fig. 30 is an enlarged portion of Fig. 29, showing the lock-off button on the disposable tang being pushed inwardly of the frame and into the locking position thereof

Figs. 31-34 are schematic sequence drawings illustrating how the improved blade of the central line kit avoids an inadvertent cut or nick of the patient's vein.

Fig. 31 illustrates, schematically, the prior art blade being positioned for enlarging the puncture previously made in the patient's skin by the needle.

Fig. 32 illustrates, schematically, how in the process of enlarging the puncture in the patient's skin, the tip portion of the prior art blade (being fairly pointed) may inadvertently cut or nick the patient's vein beneath the puncture in the skin.

Fig. 33 corresponds substantially to Fig. 31, but illustrates, schematically, the improved blade of the present invention being positioned for enlarging the puncture previously made in the patient's skin by the needle.

Fig. 34 corresponds substantially to Fig. 32 but illustrates, schematically, how the tip portion of the improved blade of the present invention (being fairly blunt) will avoid an inadvertent cut or nick of the patient's vein in the process of enlarging the puncture in the skin.

GENERAL DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to Figs. 1-3, the guarded finger scalpel 10 of the present invention includes a substantially rectangular frame 11 having a top wall 12, a bottom wall 13 and respective side portions 14 and 15 having opening 16 and 17, respectively, formed therein. A pair of spring arms 18 and 19 (or other

resilient means) are confined between the top wall 12 and the bottom wall 13 of the frame 11, being disposed rearwardly of the frame 11 as shown in Fig. 3, and extend laterally thereof through the openings 16 and 17, respectively.

These spring arms 18 and 19 are bifurcated and, preferably, are formed from a single plastic moldment (as shown more clearly in Fig. 2) and are joined together, first, at a forward portion 20 and, second, at a rearward cap 21. The forward portion 20 of the spring arms 18, 19 includes a longitudinally-extending lug 22 received within a longitudinal slotted opening 23 formed within a surgical blade 24. The lug 22 may be swaged over the blade 24 and secured thereto (as shown more clearly in Figs. 2 and 3) by hot-staking or other production process.

The blade 24 is slidably guided within a blade guide means 25 having an opening 26. The blade guide means 25 constitutes a guard means for the blade 24 and (in this embodiment) is substantially rectangular and is formed integrally with the frame 11, as for example, by a unitary plastic moldment. Preferably, the blade guide means 25 is transparent, so that the blade 24 is visible at all times (even when the blade 24 is normally confined therein).

The exposed faces of the laterally-extending spring arms are roughened, as at 27 in Fig. 1, to facilitate a manual grasping and manipulation of the guarded finger scalpel 10.

When the guarded finger scalpel 10 is thus grasped between the surgeon's thumb and forefinger (Fig. 4), the spring arms 18, 19 are squeezed together (Fig. 5) laterally inwardly of the frame 11 to thereby advance the blade 24 out of the opening 26.

Thus, the blade 24 of the guarded finger scalpel 10 of the present invention is only exposed while a cut or cuts are being made, thereby substantially reducing (if not eliminating altogether) the risks associated with using a conventional unguarded finger scalpel, not only in the highly-stressed environment of an operating room or critical care unit, but also in the subsequent clean up and disposal of the overall kit including the scalpel.

With reference again to Fig. 2, and with further reference to Fig. 6, the blade 24 and the spring arms 18 and 19 with their rearward cap 21 constitutes a subassembly 28 or inner member

nested with the frame 11. In the assembly of the guarded finger scalpel 10, the subassembly 28 is received through an opening 29 in a rear wall 30 of the frame 11. The spring arms 18 and 19 are squeezed together to clear the opening 30, and the spring arms 18, 19 are then released to enable the spring arms 18, 19 to pass through the openings 16, 17 and laterally of the frame 11. The cap 21 is then seated against the rear wall 30 of the frame 11 and may be secured thereby by protrusions (not shown) or by ultrasonic welding, hot-staking or any suitable production process.

The guarded finger scalpel 10 comprises only three parts: the molded frame 11, the molded spring arms 18 and 19, and the metal blade 24, respectively. Accordingly, the guarded finger scalpel 10 facilitates high-volume low-cost automated manufacture.

An alternate embodiment 10' of the guarded finger scalpel for the present invention is illustrated in Figs. 7-10. This guarded finger scalpel 10' has a resilient body 31, preferably of a suitable molded plastic material, and being relatively small and easy to handle and to orient. Preferably, the body 31 has complementary halves 32 and 33, respectively, joined together along a common longitudinal midplane 34 and suitably secured together, as for example, by ultrasonic welding.

A blade guide means or frame 35 is mounted within the resilient body 31, and a blade 36 is slidably guided within the frame 35. The blade 36 has respective sides 37 and 38; and a pair of spring arms 39 and 40, respectively, are connected between the sides 37, 38 and the resilient body 31.

As the resilient body 31 is squeezed between the surgeon's thumb and forefinger, as shown in Figs. 8 and 10, the respective spring arms 39 and 40 deflect, that is, are compressed towards the frame 35; and as a result, the blade 36 is advanced forwardly out of an opening 41 formed in the body 31.

Conversely, when the finger pressure is released, the respective spring arms 39 and 40 return to their original position (Figs. 7 and 9) and the blade 36 is again retracted within the body 31.

With this in mind, it will be understood by those skilled in the art that the guard means is actively disarmed and moved from

its normal position into its retracted position when the guarded finger scalpel is grasped. Conversely, the guard means is passively armed and returned to its normal position when the guarded finger scalpel is released.

The sides of the resilient body are indented, as at 42, to facilitate manual manipulation of the guarded finger scalpel 10'.

Thus, with the guarded finger scalpels 10 and 10' of the present invention, the blades 24 and 36, respectively, are exposed only when making a cut or cuts in the patient's skin. Otherwise, the blades 24, 36 are covered at all times. Accordingly, the guarded finger scalpels 10 and 10' of the present invention protect against inadvertent or accidental nicks or cuts occasionally encountered by health care providers (such as surgeons, nurses, technicians, operating room assistants and clean-up personnel) and the serious health risks associated therewith.

The protection also extends to the patient (or patients) if the surgeon or other health care provider is infected with HIV (the deadly AIDS virus) or any other contagious disease. In the event an unguarded finger scalpel becomes contaminated by tainted blood from the surgeon or other health care provider, the disease may be inadvertently communicated to the patient.

The protection afforded by the guarded finger scalpels 10 and 10' of the present invention, and the benefits and advantages of its improved method, are illustrated in Figs. 11-21.

In Fig. 11, a needle 100 is used to make a puncture 101 in a patient's arm 102 to thereby locate a vein (for example). The needle 100 is an "introducer" needle. In some cases, it may be necessary to first use a smaller "starter" needle (not shown) to locate the patient's vein. Thereafter, a flexible guide wire 103 is inserted through the needle 100 and through the puncture 101 (Fig. 12) and into the vein 104 (Fig. 13). The needle 100 is then removed and the guide wire 103 remains in the lumen, that is, within the opening in the vein, artery or intestine of the patient.

The guarded finger scalpel 10 (or 10') of the present invention is grasped by the surgeon, usually between the surgeon's thumb and forefinger (Fig. 14), and is squeezed to advance the blade 24 (Fig. 15). The blade 24 is then used to

make an incision or cut 105 in the patient's skin (Fig. 16). One or more cuts 105 may be made, thereby enlarging the puncture 101 (and facilitating the subsequent insertion of a catheter). Manual pressure is released to retract the blade 24, and the guarded finger scalpel 10 is lifted away from the cut 105.

The blade 24 is no longer exposed, and the guarded finger scalpel 10 is then discarded.

Thereafter, a catheter 106 (Fig. 18) is slipped over the guide wire 103 and through the cut 105 (Fig. 19) and into the patient's vein 104 (Fig. 20). Once the catheter 106 is in place, or while the catheter 106 is being inserted, the guide wire 103 is removed (as shown in Fig. 21).

This sequence of steps of the preferred method of using the guarded finger scalpels 10 and 10' of the present invention is illustrated in the schematic block diagram of Fig. 22.

With reference to Figs. 23-28, the guarded finger scalpel 10 is provided with a lock-off means 200. In this embodiment, the lock-off means 200 includes a lock-off button 201 carried by a side portion or wall 14 of the guarded finger scalpel 10. This lock-off button 201, as shown more clearly in Fig. 25, includes an enlarged head 202, a tapered body 203, and an enlarged foot 204, all of which, if desired, may be molded from a suitable plastic material. The lock-off button 201 may be pushed through a hole 205 in the side wall 14 and loosely retained therein between the enlarged head 202 and the enlarged foot 204. The enlarged head 202 may be roughened or knurled, as at 206 in Fig. 24, to facilitate a convenient manipulation thereof.

The forward portion 20 of the inner member (comprising the respective spring arms 18 and 19) has a blind pocket 207 formed therein. This blind pocket 207 is preferably tapered inwardly thereof and has an internal annular shelf 208 formed therein, as shown more clearly in Fig. 25.

When the surgical procedure of installing a line in a patient has been completed, and no further use of the guarded finger scalpel 10 is required, the lock-off button 201 may be pushed inwardly thereof (Fig. 24) so that its enlarged foot 204 is "popped" into the blind pocket 207 and is received firmly therein, as shown more clearly in Fig. 26. The forward portion 20 of the inner member is thereby locked to the frame 11.

Thereafter, the blade 24 cannot extend beyond the guard 25 even if the respective spring arms 19 and 20 (or one of them) is squeezed inadvertently or accidentally. This feature is very desirable in preventing nicks or cuts to the surgeon, nurse, technician or clean-up personnel while disposing of the guarded finger scalpel 10 and its overall kit. Thus, the guarded finger scalpel 10 of the present invention is provided, not only with a guard for protection while installing a line, trocar or similar medical device in a patient, but is also provided with the lock-off means 200 for protection during disposal and clean-up.

With reference to Figs. 29 and 30, a lock-off button 209 may be molded integrally with a depressible tang 210 formed by a pair of parallel slots 211 and 212, respectively, in the side wall 14 of the guarded finger scalpel 10.

With reference to Figs. 31-34, the kit of the present invention includes an improved blade on the guarded finger scalpel, thereby preventing accidental nicks or cuts in the patient's arm while using the guarded finger scalpel to enlarge the puncture in the patient's skin (the puncture being previously made by the needle in the kit).

Fig. 31 and 32 illustrate, schematically, the problem occasionally encountered in the prior art. The blade 24 has a forward portion with a fairly pointed tip 300, and the acute angle A formed between the lower edge 301 and the front edge 302 is approximately 30°. This blade 24 is typically referred to in the art as a "No. 11 Blade" and is used extensively in central line kits.

As a result of this pointed tip configuration, it is not at all unusual for the blade 24 to inadvertently or accidentally pierce (or nick or cut) the patient's vein 104 in the process of enlarging the puncture 105 (as illustrated in Fig. 32).

To avoid this problem, and as shown in Fig. 33, the improved blade 303 of the present invention has a forward portion which is less pointed and more blunt than that of the prior art blade 24. The acute angle B defined between the lower edge 304 and the front edge 305 is more than 45° and, in the preferred embodiment, approximately 60°.

As a result of the tip configuration of the improved blade 303 of the present invention, and as shown in Fig. 34, the

possibility of inadvertently or accidentally cutting or nicking the patient's vein 104 is substantially reduced (if not eliminated altogether)..

Obviously, many modifications may be made without departing from the basic spirit of the present invention. For example, instead of the patient's vein (as shown herein) the flexible guide wire 103 may be inserted into a patient's organ, vessel or body cavity under certain circumstances during a surgical procedure. Also, the guarded finger scalpel may be used by any health care provider, such as a cardiologist, pulmonary doctor, anesthesiologist, nurse, etc. Accordingly, it will be appreciated by those skilled in the art that within the scope of the appended claims, the invention may be practiced other than has been specifically described herein.

CLAIMS

1. In a kit for a central line to be installed in a patient, the combination of a needle for making a puncture in the patient's skin above one of the veins, a guarded finger scalpel having a blade attached thereto for enlarging the puncture in the patient's skin, guard means on the guarded finger scalpel, the guard means having a normal position in which the blade is covered and further having a retracted position in which the blade is exposed, and the blade including a tip portion having a front edge and a lower edge forming an acute angle therebetween, the acute angle being sufficiently large to prevent the blade from cutting into the vein adjacent to the puncture in the patient's skin.

2. The combination of claim 1, wherein the acute angle is greater than 45° .

3. The combination of claim 2, wherein the acute angle is approximately 60° .

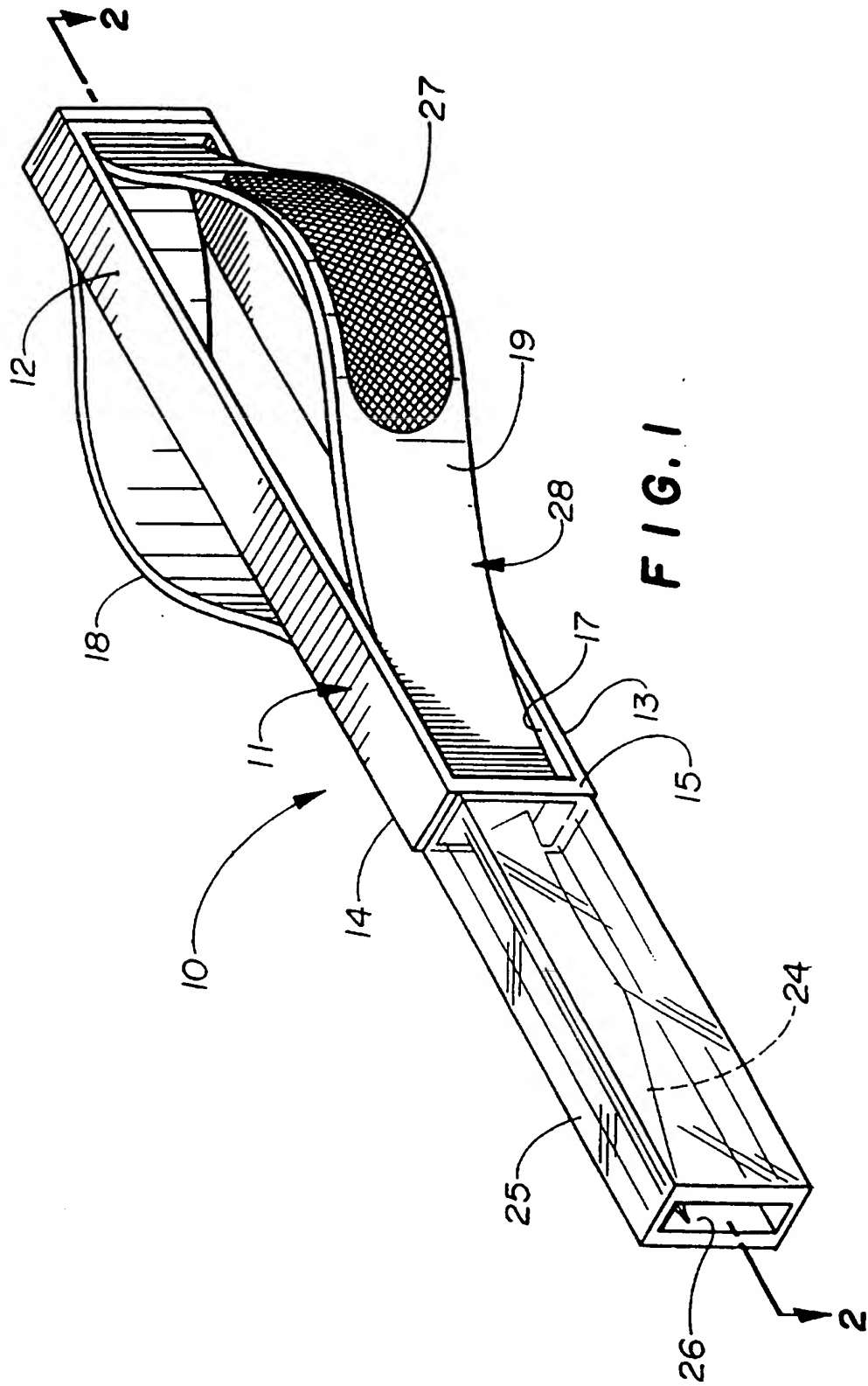
4. The combination of claim 1, wherein the guard means is actively disarmed and moved from its normal position into its retracted position when the guarded finger scalpel is grasped and is further passively armed and returned to its normal position when the guarded finger scalpel is released.

5. The combination of claim 1, wherein the guarded finger scalpel includes a body normally intended to be grasped between the surgeon's thumb and forefinger, the body comprising a frame including a pair of side walls having respective openings therein, wherein an inner member is confined within the frame and is guided for slidable movement therein, the inner member carrying the blade thereon, and the guard means comprising at least one spring arm carried by the inner member and extending through a respective opening in the frame.

6. The combination of claim 1, further including a lock-off means operative in the normal position of the guard means and

preventing movement of the guard means from its normal position into its retracted position, thereby preventing blade exposure and protecting the clean-up personnel in the hospital against inadvertent nicks or cuts during disposal of the kit.

7. In a kit for a central line to be installed in a patient, the combination of a needle for making a puncture in the patient's skin above one of the veins, a guarded finger scalpel having a blade attached thereto for enlarging the puncture in the patient's skin, guard means on the guarded finger scalpel, the guard means having a normal position in which the blade is covered and further having a retracted position in which the blade is exposed, the guard means being actively disarmed and moved from its normal position into its retracted position when the guarded finger scalpel is grasped and further being passively armed and returned to its normal position when the guarded finger scalpel is released, a lock-off means operative in the normal position of the guard means and preventing movement of the guard means from its normal position into its retracted position, thereby preventing blade exposure and protecting the clean-up personnel in the hospital against inadvertent nicks or cuts during disposal of the kit, and the blade including a tip portion having a front edge and a lower edge forming an acute angle therebetween, the acute angle being approximately 60° to prevent the blade from cutting into the vein adjacent to the puncture in the patient's skin.



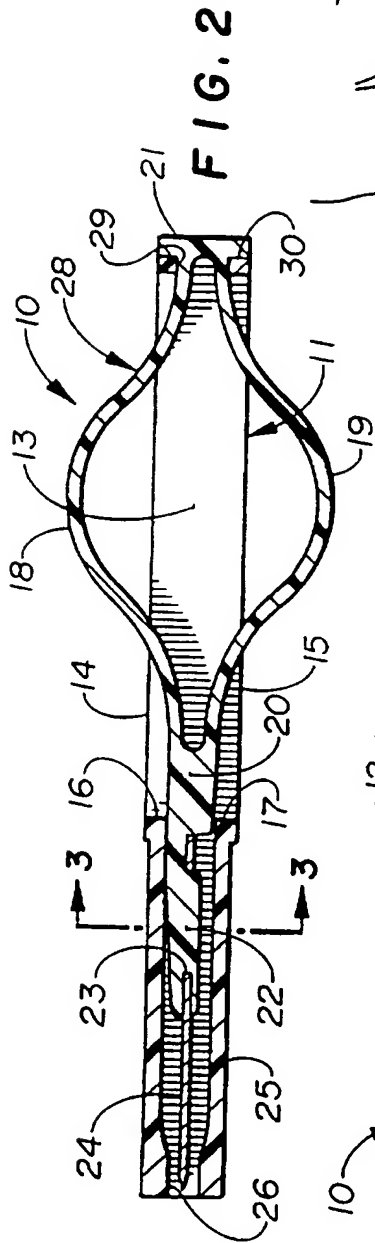


FIG. 2

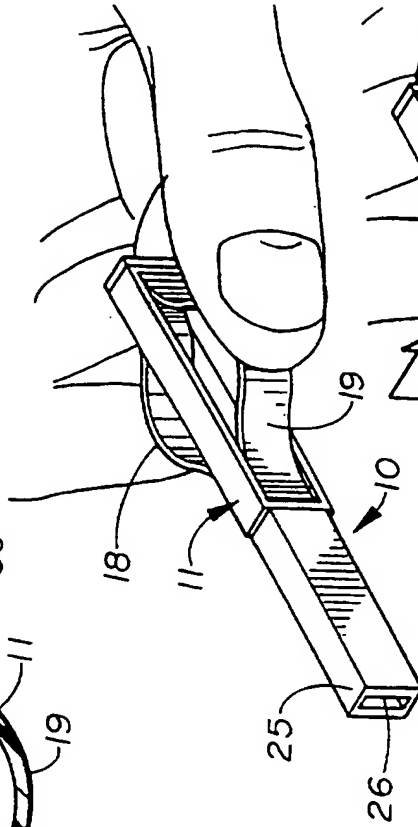


FIG. 4

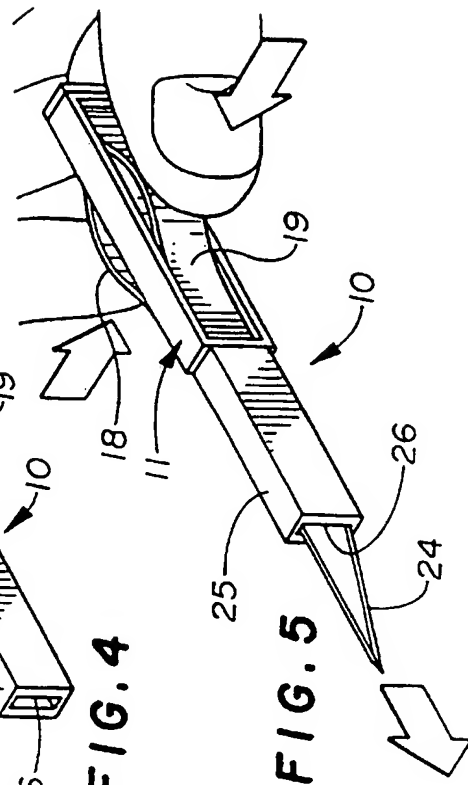


FIG. 5

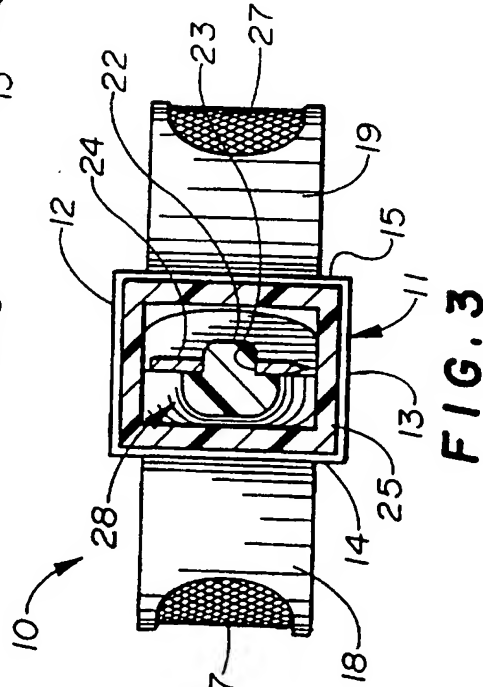
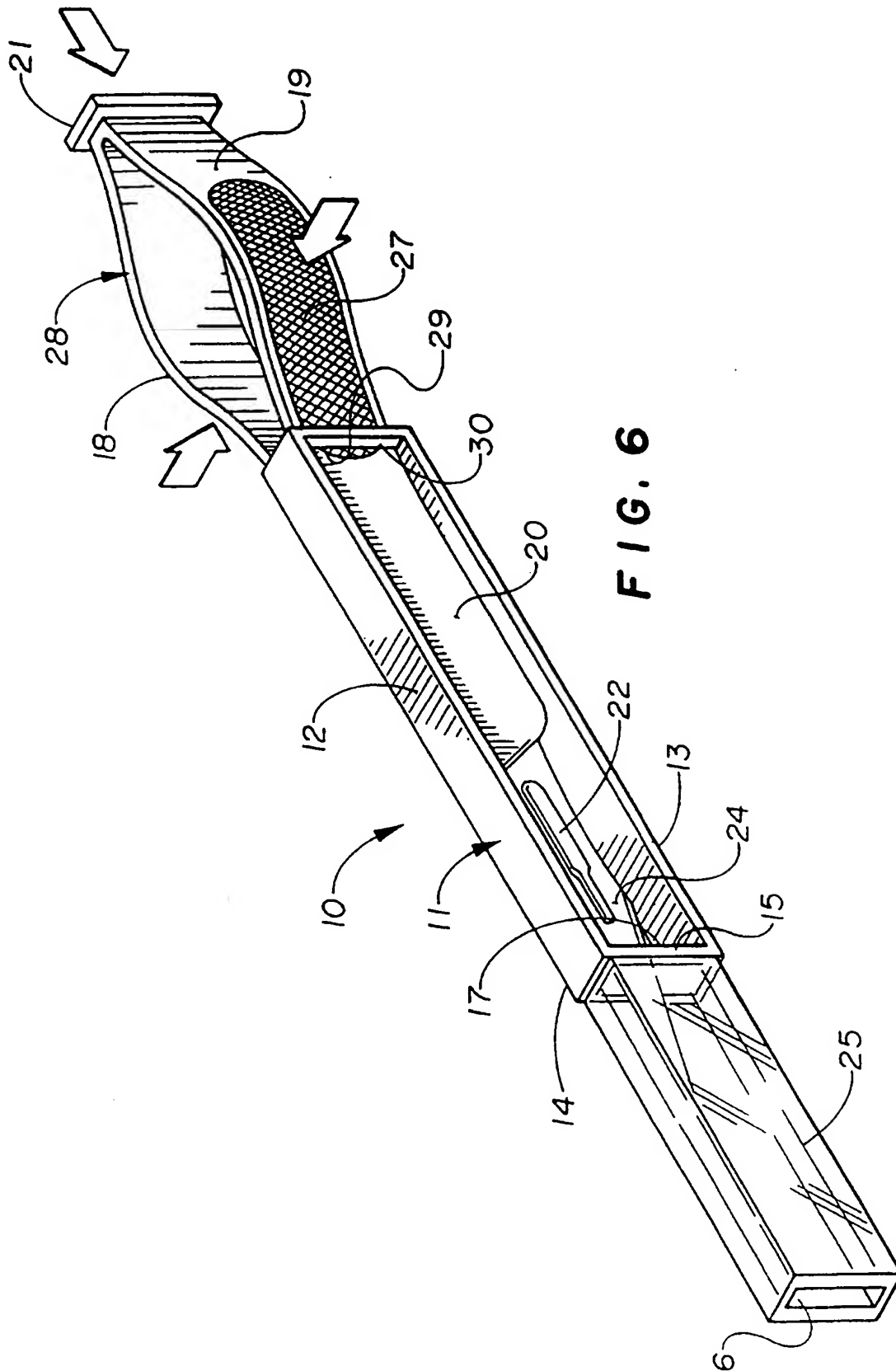


FIG. 3



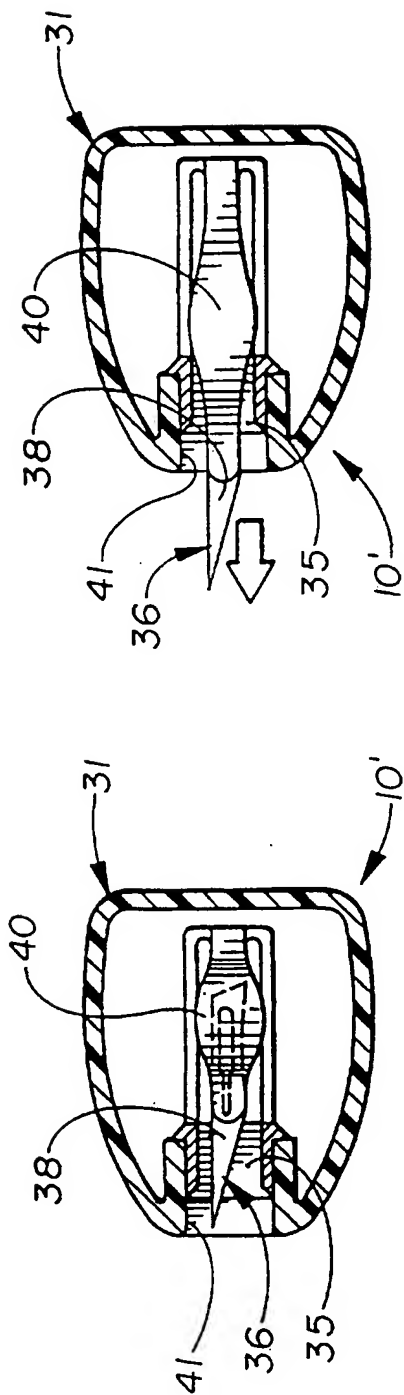


FIG. 8

FIG. 7

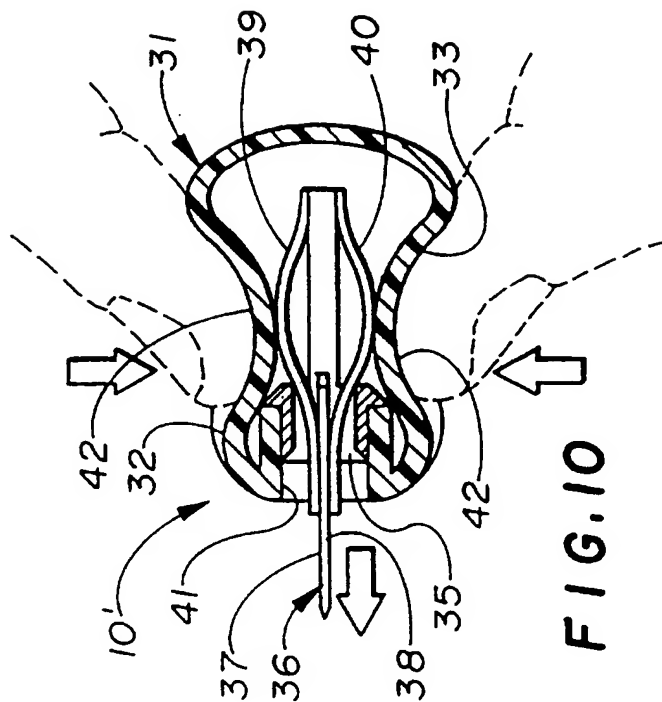


FIG. 10

FIG. 9

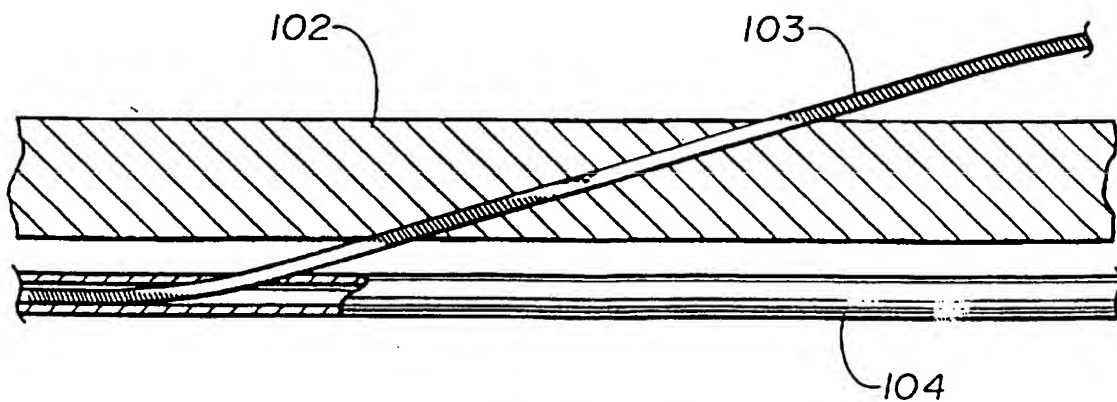
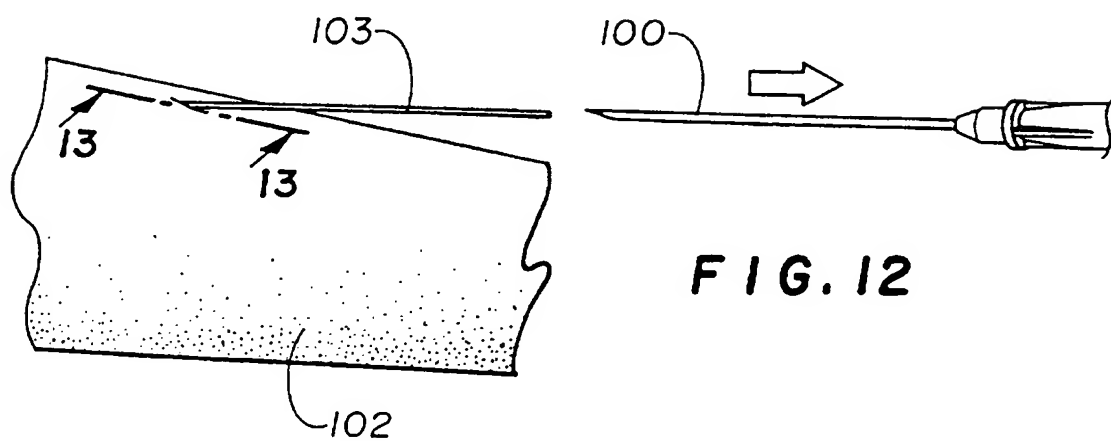
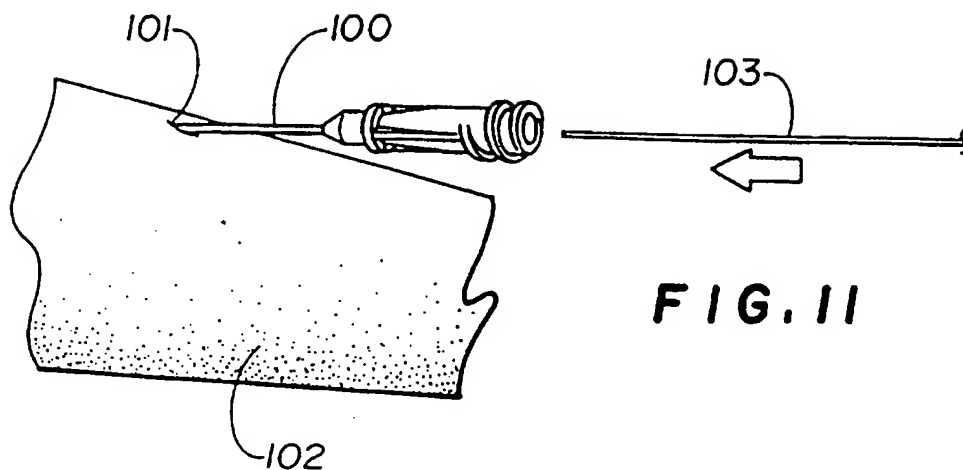


FIG. 13
5/14

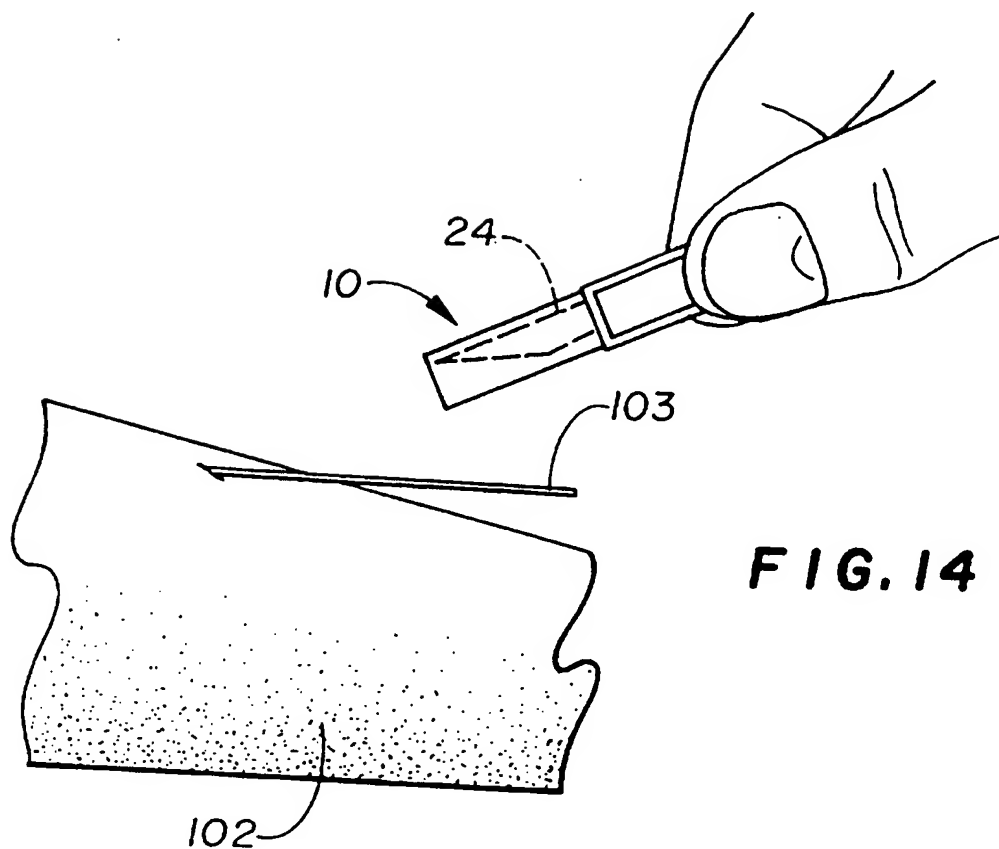
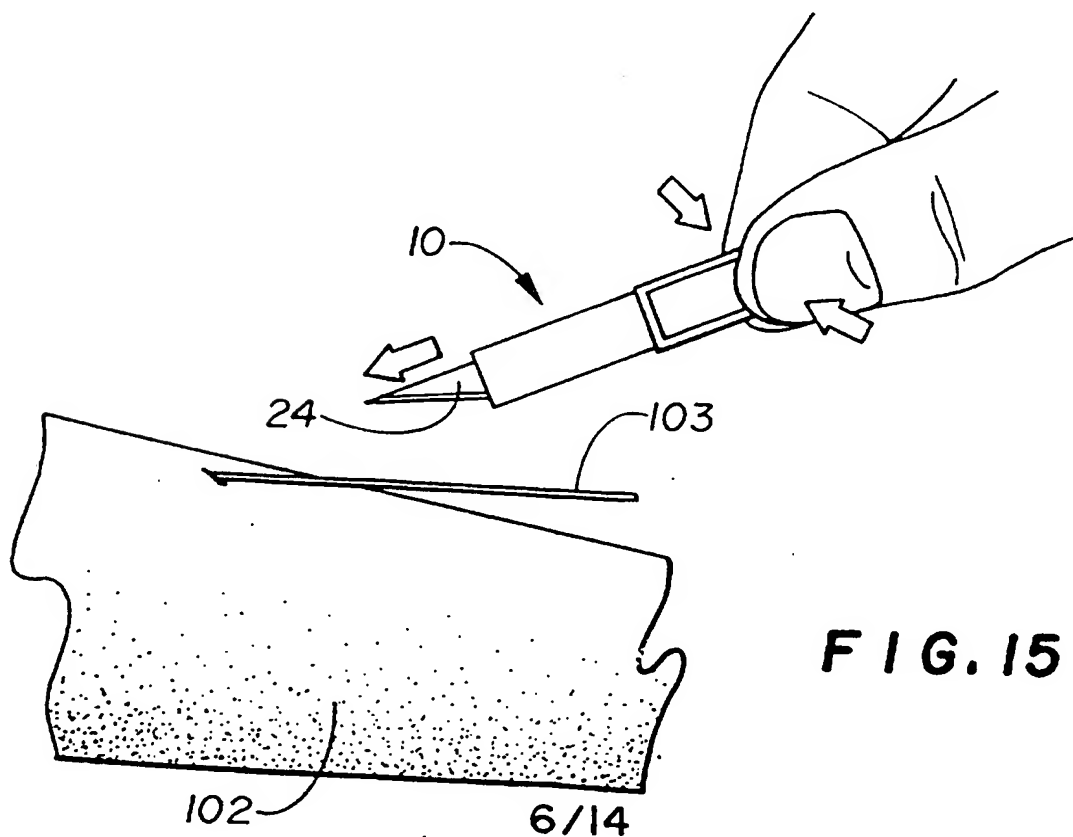
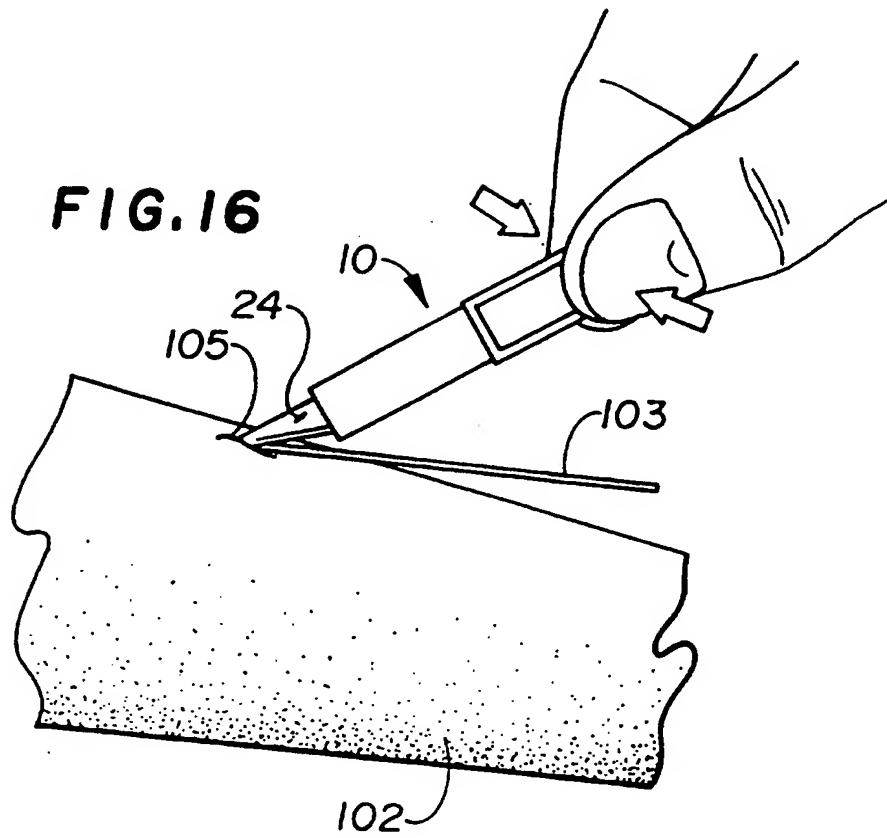
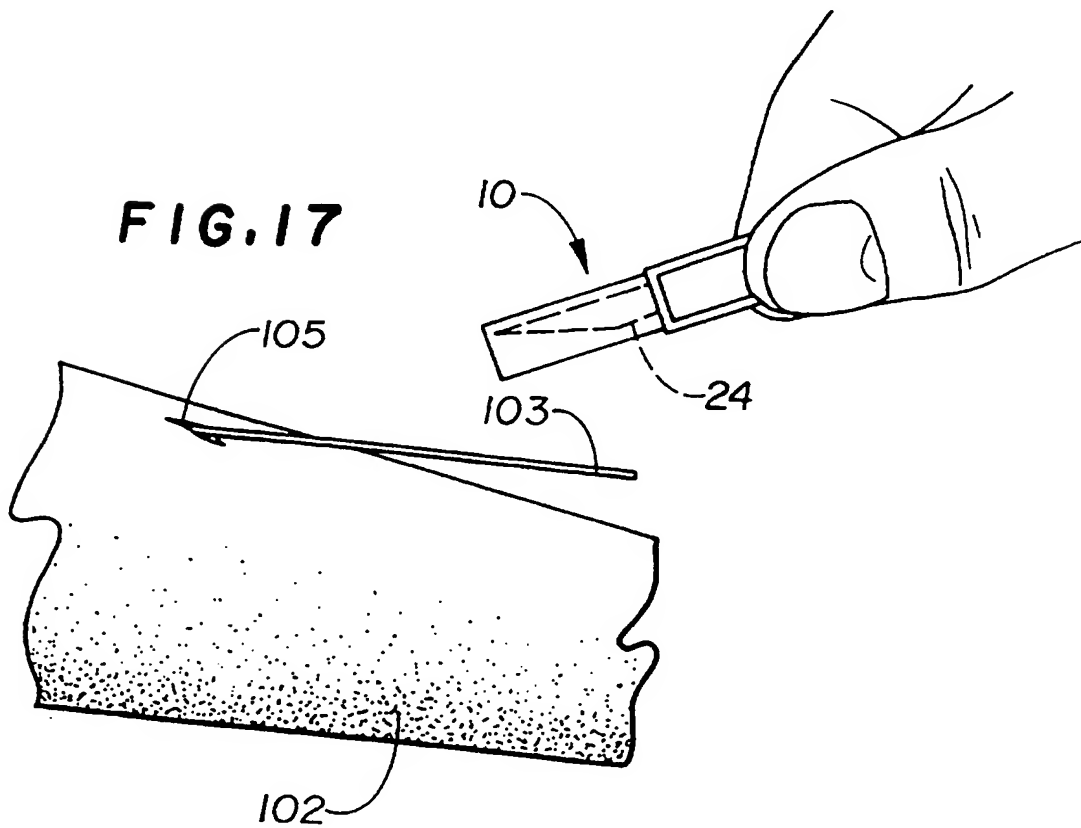
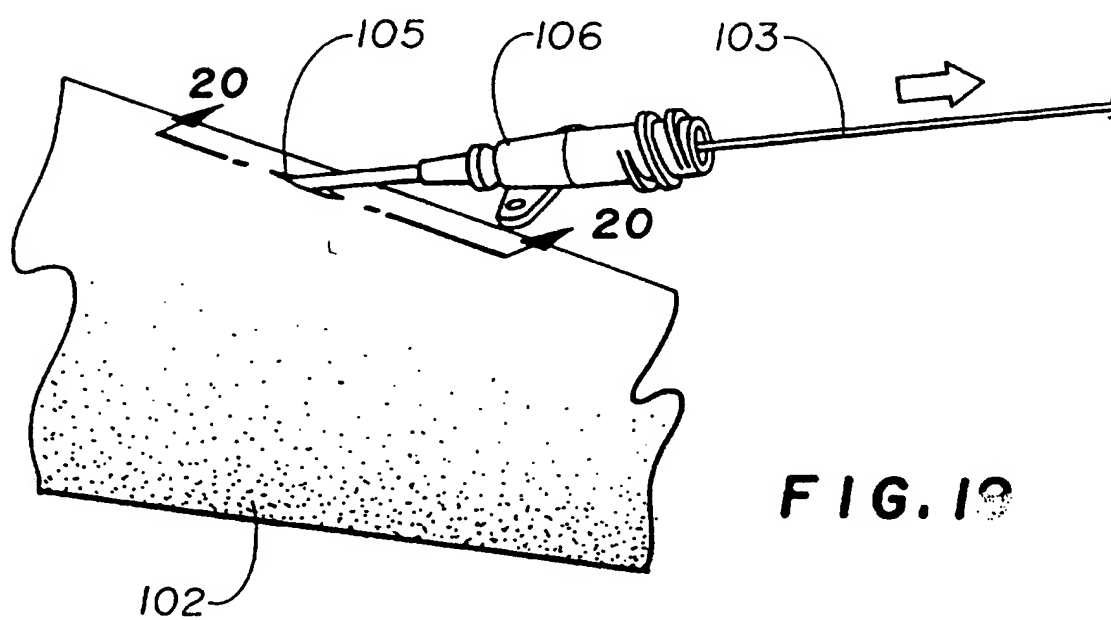
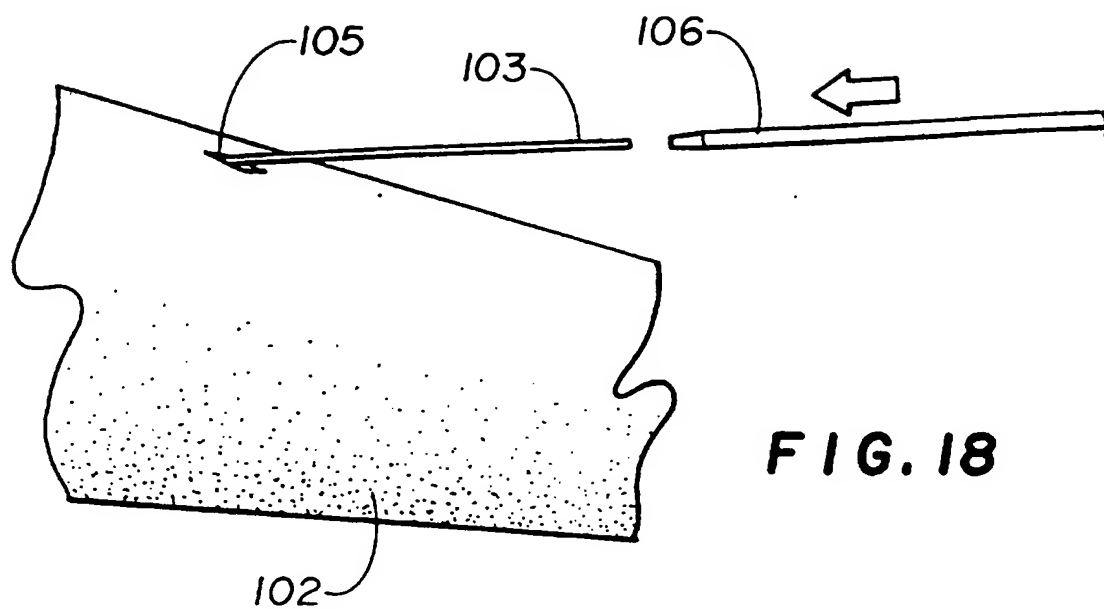
**FIG. 14****FIG. 15**

FIG. 16**FIG. 17**



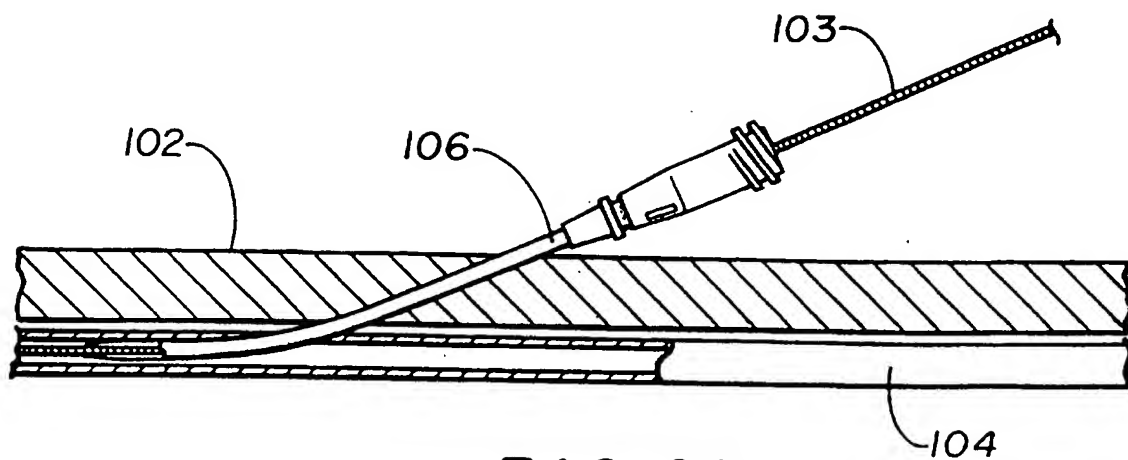


FIG. 20

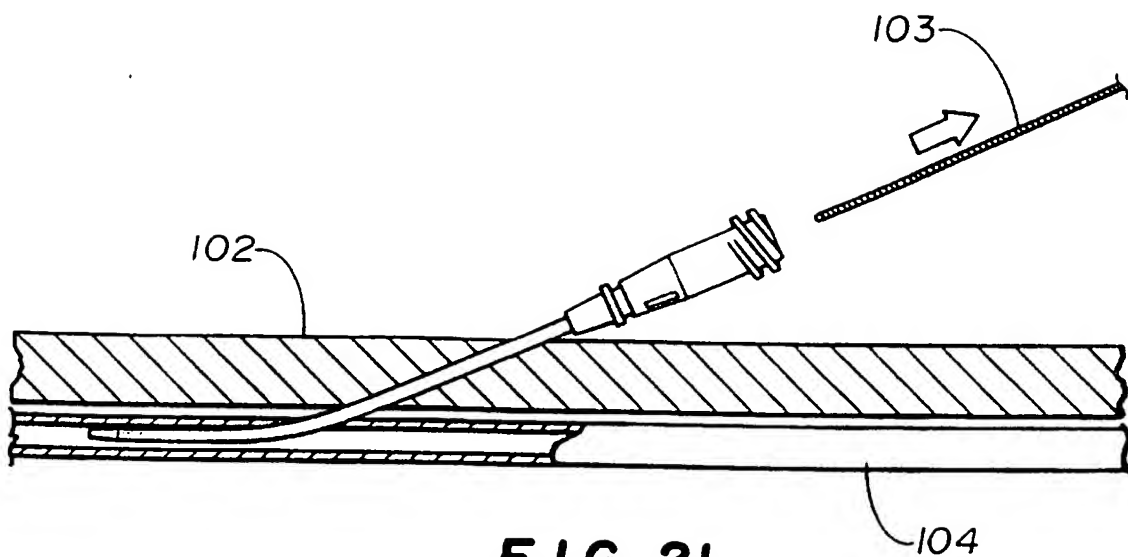


FIG. 21

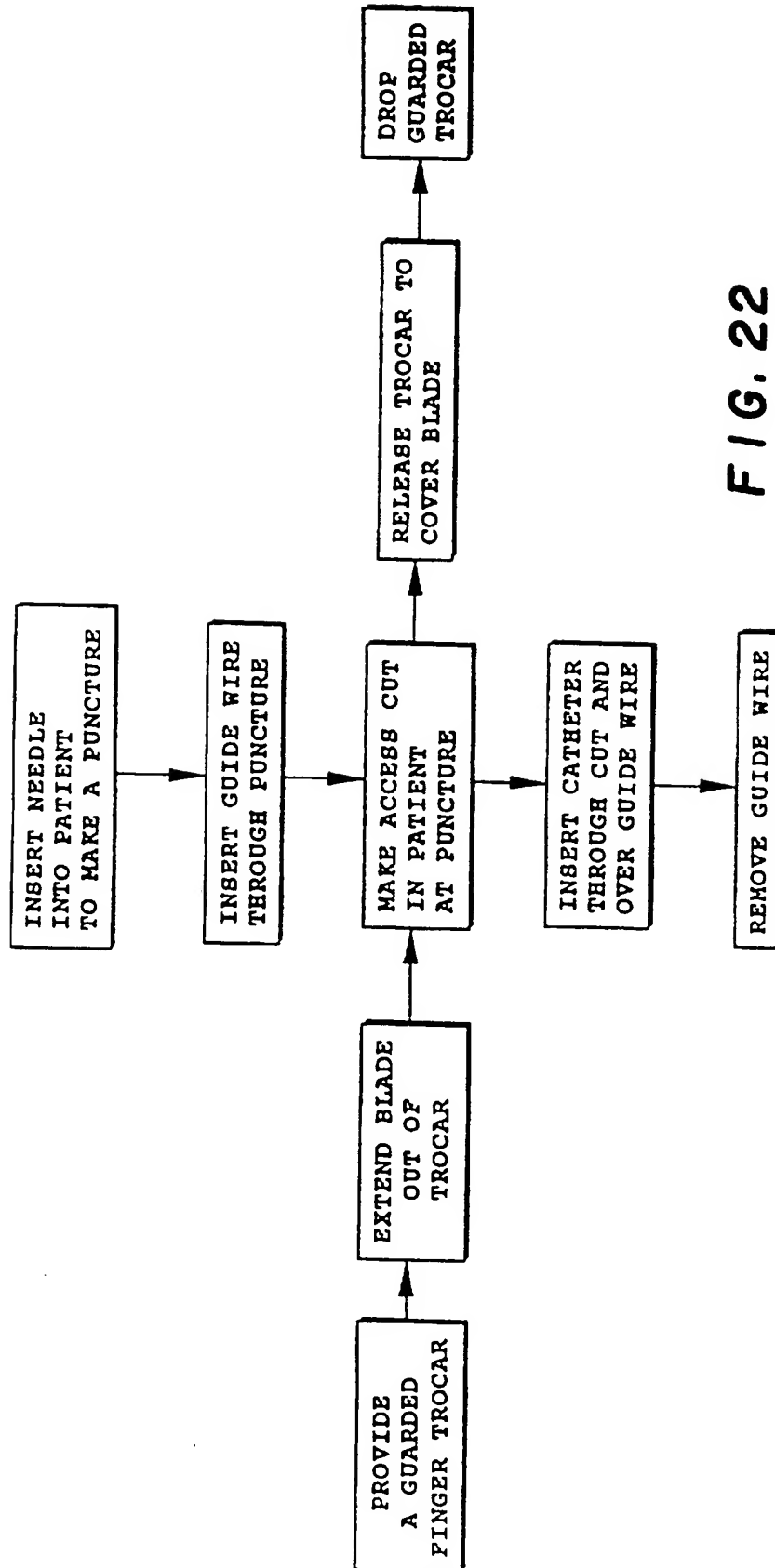
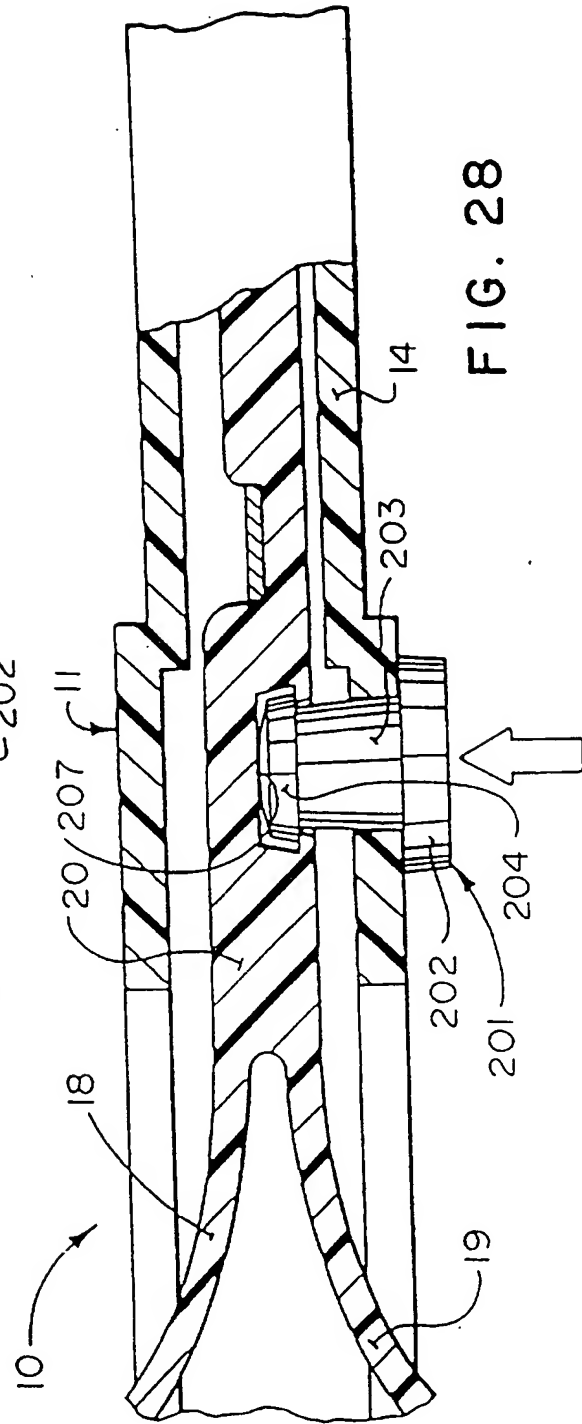
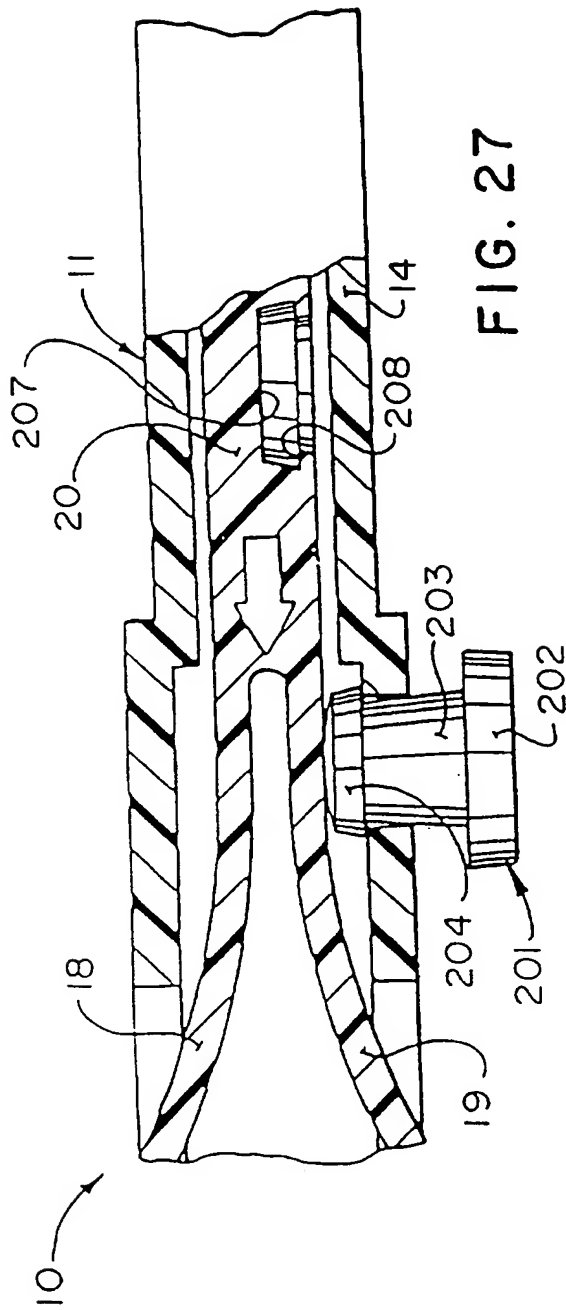
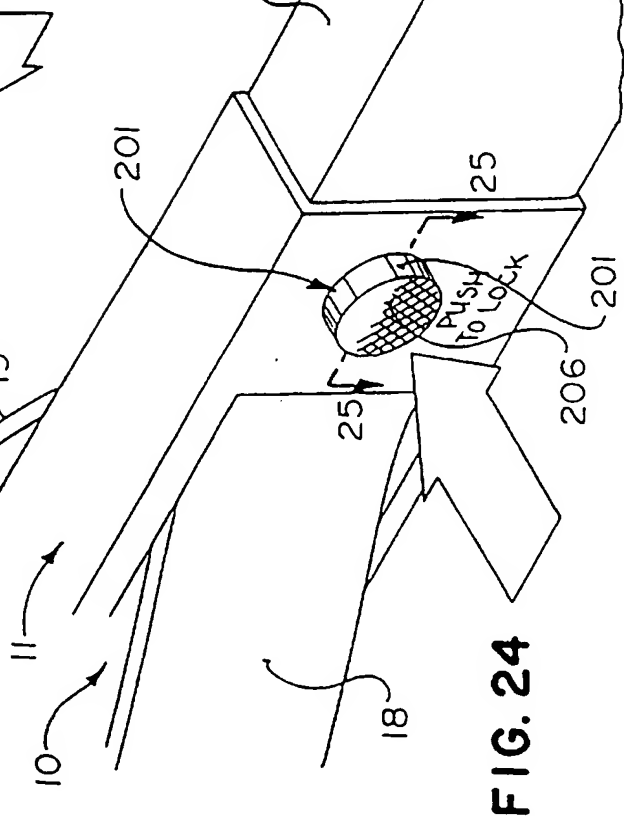
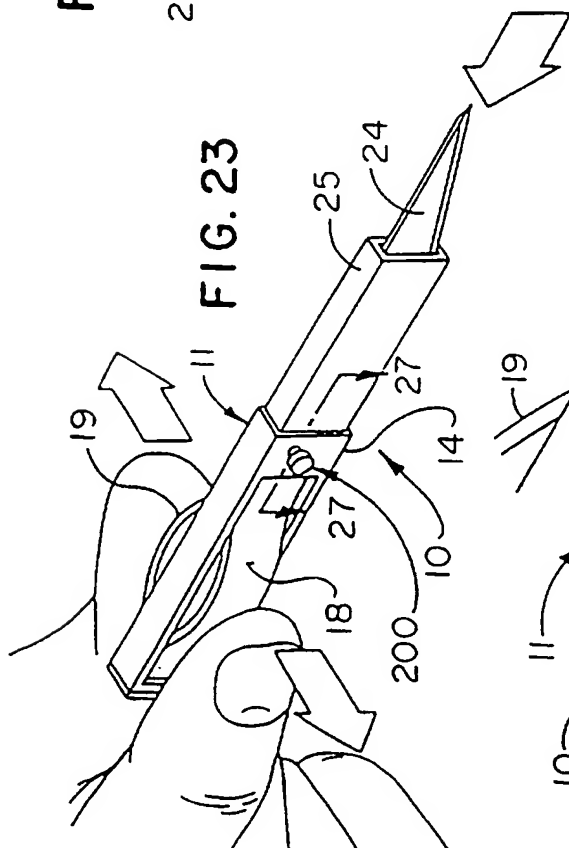
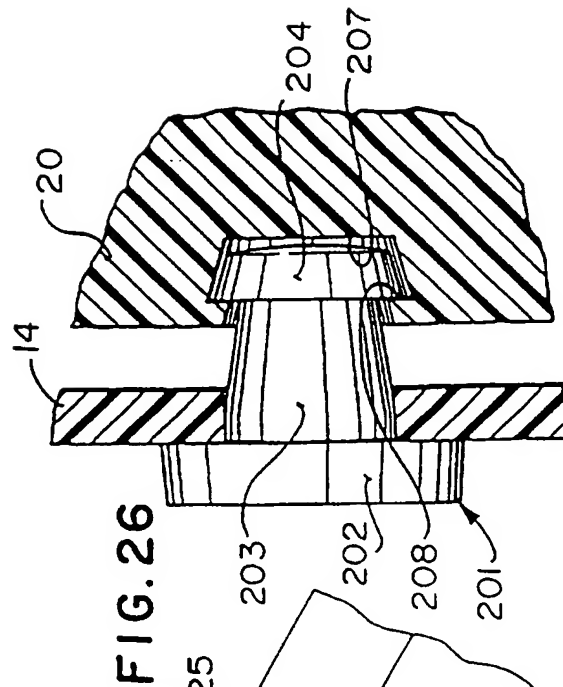
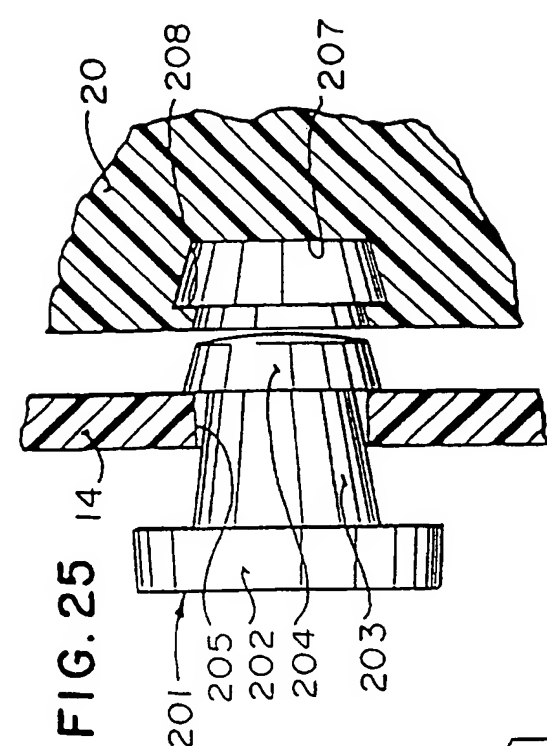


FIG. 22





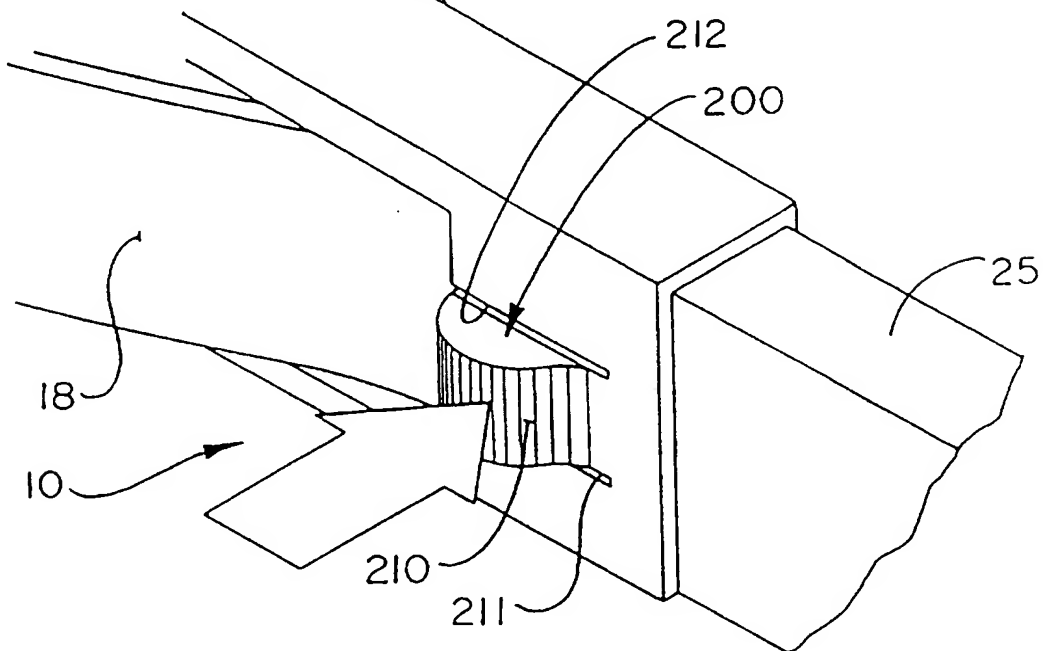
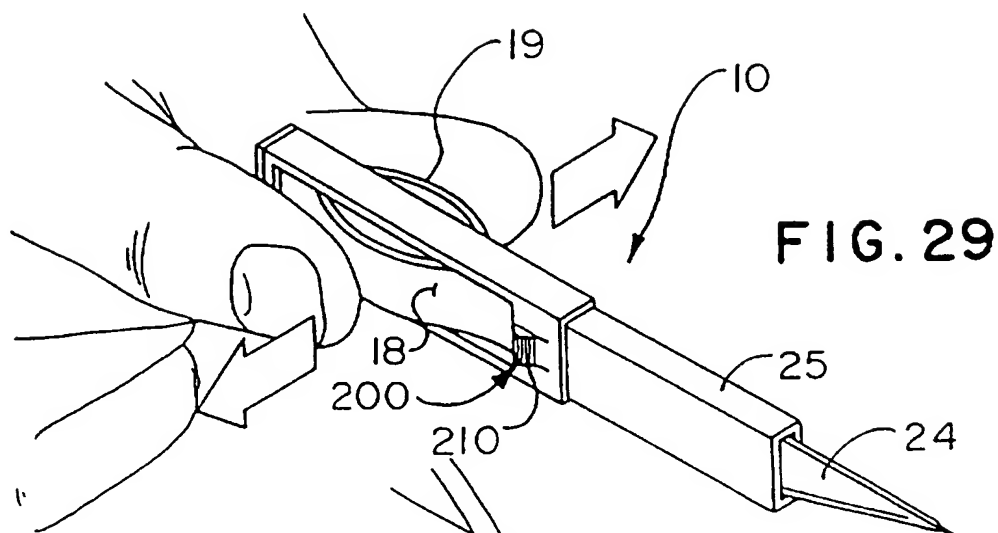


FIG. 30

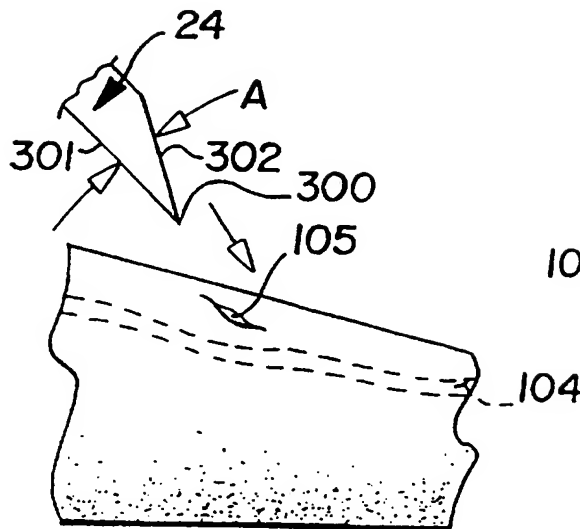


FIG. 31
PRIOR ART

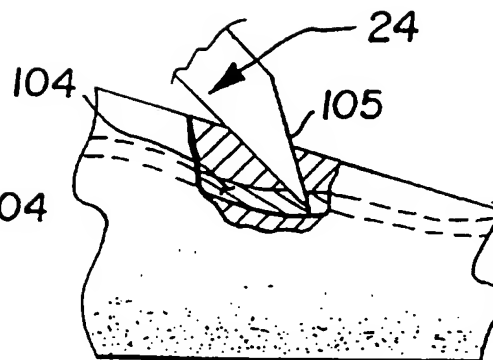


FIG. 32
PRIOR ART

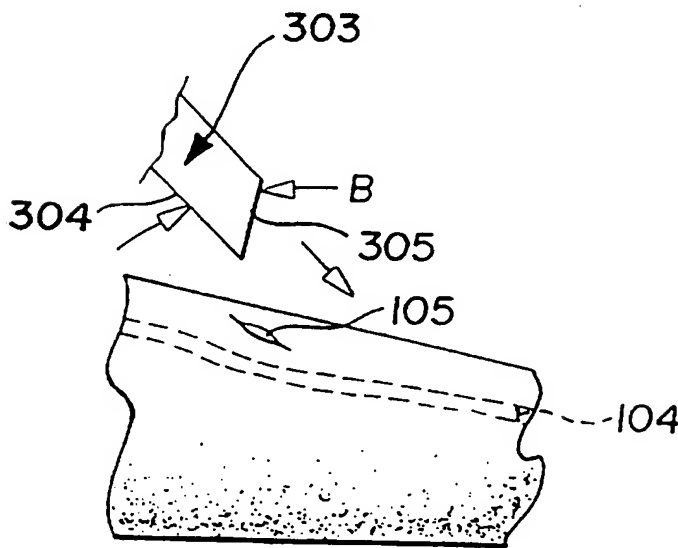


FIG. 33

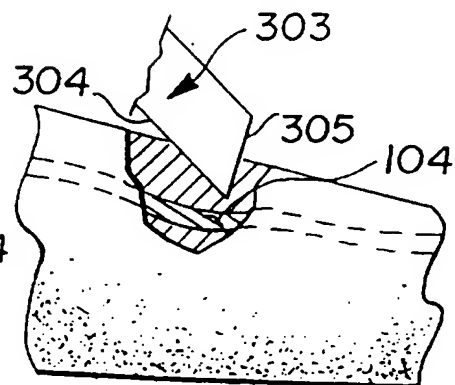


FIG. 34

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/05768

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/32

US CL :30/162; 606/167, 182, 185

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 30/162; 606/167, 170, 172, 181, 182, 185, 189

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,186,168 A (SPOFFORD et al.) 16 February 1993, claim 14.	1-7
Y	US 5,208,983 A (MASSE) 11 May 1993, Figs. 1-5.	1-7
A	US 5,370,654 A (ABINDIN et al.) 06 December 1994.	1-7
A,P	US 5,545,175 A (ABINDIN et al.) 13 August 1996.	1-7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" documents of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" documents member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

20 MAY 1997

Date of mailing of the international search report

24 JUN 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231Authorized officer
PATRICK RASCHE

Facsimile No. (703) 305-3230

Telephone No. (703) 308-3523

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.